REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on 7/13/07, the Examiner rejected claims 6-49.

Interview

The Applicants representative and the Examiner conducted an in person interview on 9/13/07. The topics discussed are included in the claim amendments and the remarks section of this document.

Information Disclosure Statement

An information disclosure statement is being submitted including references newly presented to the Applicant's representative.

Double Patenting

In the Office Action, the Examiner noted that claims 6-11, 15, and 19 are rejected under the judicially created doctrine of obviousness-type double patenting for reciting subject matter that is unpatentable over claims 6-11, 15, and 19 of copending application 10,269,422 in view of U.S. Pat. No. 5,522,798 to Johnson. It is requested that the obviousness-type double patenting rejection be held in abeyance until all other issues have been resolved in the above-referenced application.

Rejections under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 6, 8-10, 12-13, 15, 20-21, and 41-43 under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,088,981 to Howson in view of U.S. Pat. No. 5,522,798 to Johnson. Applicants respectfully traverse.

Independent claim 6 has been amended to clarify the distinction between the claimed invention and the cited references. In particular, the term **probability of effectiveness** has been clarified in reference to the field of pharmacodynamics so as to distinguish from pharmacokinetic terms such as: **effect** site concentration, **effect** compartment concentration, and dosage.

> 6. (Currently Amended) A system for data representation, comprising:
> a drug delivery system;
> a data stream device; and
> a drug display monitor in communication with the data stream device, the drug display monitor configured to depict, in real time, a present probability of effectiveness of at least one drug introduced into the subject by the drug delivery system and future probabilities of effectiveness of the one or more drugs in the subject, wherein the present probability of effectiveness includes a **correlation** of a predicted drug concentration based on modeled pharmacokinetic data and a probability of pharmacodynamic effectiveness based on modeled pharmacodynamic data.

Howson and Johnson utilize **pharmacokinetic** data to predict drug concentrations (effect site concentrations) in association with delivering drugs at a particular rate but fail to **correlate** the predicted concentrations with pharmacodynamic data of any type. Therefore, Howson and Johnson independently and in combination fail to teach displaying a **probability of effectiveness** because they are limited to independently analyzing pharmacokinetic data for purposes of achieving a pharmacokinetic result (concentration). The study of pharmacodynamics is based on accurately determining the effects of a drug upon the body as opposed to the study of pharmacokinetics which is based on determining the body's effect on the drug (ie.

concentration). While particular concentrations may be commonly **assumed** to produce a particular effect, this assumption may be false. Unfortunately, numerous well known clinical cases have occurred in which a patient experienced pain or regained consciousness despite the assumption that the particular effect site concentration was sufficient to maintain the desired pharmacodynamic effect (ie. anesthesia, analgesia, NMB). The study of pharmacodynamics is based on accurately predicting how the body responds to a particular drug.

In particular, Howson teaches a system for programming a desired flow rate for a portable infusion pump so as to achieve a desired concentration (Pk). Abstract. While Howson may use pharmacokinetic (PK) models 26 with a display 28 to predict plasma and effect-site concentrations in the past, present and future, it does not **correlate** pharmacodynamic (PD) models with effect-site concentration to **accurately** predict a probability of pharmacodynamic effect such as sedation, analgesia, and NMB. Rather, a user of Howson is forced to **interpret/assume/calculate** that a particular concentration has a desired pharmacodynamic effect.

Likewise, Johnson teaches an infusion pump system that considers pharmacokinetic data in creating a flow rate designed to achieve a particular concentration (Pk). While Johnson may use pharmacokinetic (PK) models to predict a concentration (Figure 5 elements, 126, 128, 132), it does not **correlate** pharmacodynamic (PD) models with the predicted concentrations to **accurately** predict a probability of pharmacodynamic effect such as sedation, analgesia, and NMB. Rather, a user of Johnson is forced to **interpret/assume/calculate** that a particular concentration has a desired pharmacodynamic effect.

For at least these reasons, Applicants request that the rejection of independent claim 6 be withdrawn. Likewise, claims 8-10, 12-13, 15, 20-21 and 41-43 are dependent from claim 6 and

are allowable for at least the same reasons. In addition, NEW dependent claim 50 is dependent from claim 6 and is therefore allowable for at least these reasons.

In the Office Action, the Examiner rejected claims 7 and 11 under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,088,981 to Howson in view of U.S. Pat. No. 5,925,014 to Teeple. Applicants respectfully traverse.

Claims 7 and 11 are dependent from independent claim 6 and therefore are allowable for at least the reasons stated above.

In the Office Action, the Examiner rejected claims 14, 22-34, 35-40, and 44-49 under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,088,981 to Howson in view of U.S. Pat. No. 5,522,798 to Johnson and further in view of U.S. Pat. No. 5,925,014 to Teeple. Applicants respectfully traverse.

Independent claim 14 has also been amended to clarify the distinction between the claimed invention and the cited references. In particular, the term **probability of effectiveness** has been clarified in reference to the field of pharmacodynamics so as to distinguish from pharmacokinetic terms such as: effect site concentration, effect compartment concentration, and dosage.

14. (Currently amended) A system for data representation, comprising:
a processor, comprising drug models, producing an internal representation of drug display data and decoding a data stream;
a memory unit in communication with the processor;
a long term memory unit in communication with the processor;
a graphics adapter in communication with the processor; and
a display monitor in communication with the graphics adapter and configured to depict,
graphically and substantially in real-time, a modeled probability of effectiveness of at least one drug in a subject at:
causing the subject to lose consciousness;
eliminating or blocking laryngoscopy pain, incision pain, or intraoperative pain; or
causing a measurable level of muscle relaxation~~.~~;

wherein the probability of effectiveness includes a **correlation** of a predicted drug concentration based on modeled pharmacokinetic data and a probability of pharmacodynamics effectiveness based on modeled pharmacodynamic data.

As discussed above with reference to independent claim 6, Howson and Johnson fail to teach **correlating** concentration with pharmacodynamic data of any type. Teeple also teaches an infusion pump type system that utilizes pharamacokinetic data to determine an appropriate flow rate so as to achieve a desired effect site concentration. Figure 4 illustrates a chart of **infusion rates** designed to achieve particular effect site concentrations for particular drugs. The prediction of a drug concentration, effect site concentration, or effect compartment concentration still requires that a user **interpret/assume/calculate** that a particular concentration has a desired pharmacodynamic effect. Teeple fails to correlate the predicted pharmacokinetic concentrations with pharmacodynamic data.

Therefore, for at least the reasons stated above, Applicants request that the Examiner withdraw the rejection of independent claim 14. Claims 22-34 are dependent from claim 14 and are therefore allowable for at least the same reasons.

Independent claim 35 has also been amended to clarify the distinction between the claimed invention and the cited references. In particular, the term **probability of effectiveness** has been clarified in reference to the field of pharmacodynamics so as to distinguish from pharmacokinetic terms such as: effect site concentration, effect compartment concentration, and dosage.

35. (Currently amended) A system for modeling and displaying a probability of desired effectiveness of at least one drug in a subject, comprising:

a processing element programmed to model a concentration of at least one drug in a subject over time; and

an output element configured to display, substantially in real-time, a modeled concentration of the at least one drug normalized in reference to at least one concentration at which the at least one drug will have a desired pharmacodynamic effect

on a known percentage of a population based on a **correlation** of the modeled concentration and a set of modeled pharmacodynamic data for the corresponding at least one drug.

As discussed above, Howson, Johnson, and Teeple alone and in combination fail to teach **correlating** pharmacokinetic and pharmacodynamic data. In addition, these references fail to teach **normalizing** concentration with pharmacodynamic effect. For example, normalizing a Propofol pharmacokinetic concentration plot with a pharmacodynamic modeled probability that a particular concentration will cause 95% of the population to be sedated. One embodiment of this type of normalization is illustrated in the originally filed application Figures 23 and 24 and described on pages 42-43 of the original specification. The left 2/3 of the display represents a time based concentration plot normalized to a particular pharmacokinetic probability of effect (EC95 value).

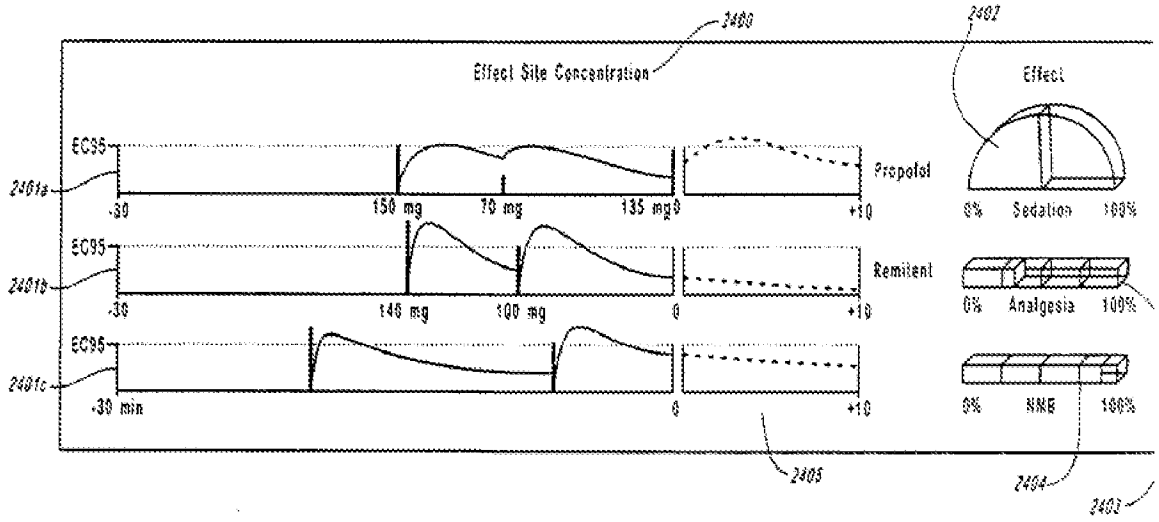

FIGURE 24

For at least these reasons, Applicants request that the rejection of independent claim 35 be withdrawn. Likewise, claims 35-40 and 44-49 are dependent from claim 35 and are therefore allowable for at least the reasons stated above.

CONCLUSION

Applicants submit that the amendments made herein do not add new matter and that the claims are now in condition for allowance. Accordingly, Applicants request favorable reconsideration. If the Examiner has any questions or concerns regarding this communication, the Examiner is invited to call the undersigned directly at 801-533-4095 or email at trent@bakeriplaw.com .

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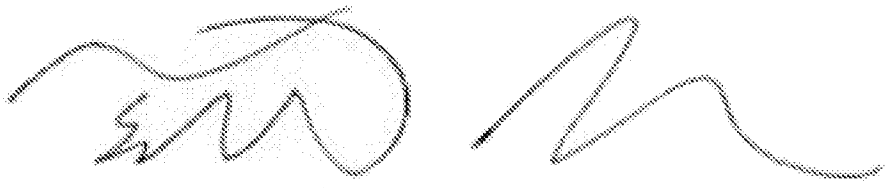
Respectfully submitted,



Trent H. Baker
Attorney for Applicants
Registration No.: 46,534

BAKER & ASSOCIATES PLLC
470 East Ninth Avenue
Salt Lake City, Utah 84103
Telephone: (801) 533-4095
Facsimile: (801) 665-1358